

Remarks

Applicants have received and carefully reviewed the Office Action mailed November 19, 2007. Claims 20-29 are pending. Reconsideration and allowance of the pending claims are respectfully requested.

Rejections under 35 U.S.C. § 103(a)

Claims 20-29 are rejected as being unpatentable over Mathews (US 6,033,406) in view of Luque (US 4,790,297) and Foley (US 5,792,044) and Davison (US 2001/0011170). The Examiner acknowledges that Mathews only teaches a method involving inserting a fusion device between a first and second vertebrae, and fails to teach performing a two level fixation procedure spanning two intervertebral spaces between three vertebrae, as is recited in the claims. The Examiner also acknowledges that Mathews fails to teach advancing a decompression tool into the surgical site to perform a decompression procedure on the vertebrae, and inserting an access device in a first configuration through an incision of the skin until a distal portion is located adjacent the spine, actuating the access device to a second configuration having an enlarged cross-sectional area at the distal portion spanning at least a portion of the first, second, and third vertebrae, and performing the surgical procedures through the access device, as recited in the claims.

The Examiner relies on Luque for teaching a method of performing a two level fixation procedure, and Foley for teaching a method involving insertion of a decompression tool to perform a decompression procedure on vertebrae. The Examiner also relies on Davison for teaching a method involving inserting an access device until a distal portion is located adjacent the spine, actuating the device to a configuration having an enlarged cross-sectional area at the distal portion spanning at least a portion of first, second, and third vertebrae, and performing various surgical procedures, such as decompression and fixation through the access device. The Examiner then asserts that it would have been obvious to one of ordinary skill in the art to perform the method of Mathews modified by Luque and Foley, through the access device of Davison in order to fix multiple joints of the spine, to reduce the pressure on the spinal cord, and to provide a larger working area while reducing the amount of trauma experienced by the patient. Applicants respectfully disagree.

While Luque does appear to teach a method of fixing a plurality of levels of vertebrae, Luque does not appear to provide any suggestion, motivation or guidance for performing this procedure through an access device such as that taught by Davison. Luque teaches:

The surgical technique of the preferred spinal fixation method of the present invention consists first of a normal posterior midline approach to the spinal column. It is preferred that this be done by dissecting the dermis with a sharp scapel and from there on using a Bovi on six coagulation, which provides the coagulation and cutting qualities that permit an almost bloodless subperiosteal dissection to the spinous process through the entire posterior vertebral elements up to the tip of the transverse process bilaterally. After the exposure, bony or soft tissue correction may be done to overcome any pathology.

Emphasis added; see column 4, lines 42-53. Luque then teach:

As a safety feature, a plurality of guide wires 17 are introduced through the cancellous bone. The guide wires 17 are expected to deflect if directed against the cortical bone. This perforation of the soft bone of the pedicle is always done under direct vision and introduced into the middle of the vertebral body.

...

A cannulated screw tap 63 is then introduced over the guide wires 17 and through the pedicle to form a threaded aperture 64 in the vertebrae V as will now be apparent to those skilled in the art. ... If any guide wire 17 is bent or deformed, it must be removed and replaced with a straight guide wire 17 (passing the screw tap 63 or screw 15 over a bent guide wire 17 could cause the guide wire 17 to advance an undesirable distance).

...

With all the guide wires 17 aligned, the appropriate size plate 13 is then placed over the guide wires 17 so that all the guide wires 17 pass through the slot 23. ...Prior to seating the screws 15 into the plate 13, adjustments for lordosis, kyphosis compression or distraction are done with clamps or with a joy stick action with the driver 65 on the screws 15, individually and segmentally.

...

When adequate correction and alignment is obtained, the screws 15 are snugged down onto the corresponding concaved depressions 25 of the plate 13, each screw 17 fitting at the appropriate place and fixed firmly at the desired position. The guide wires 17 are then removed.

Emphasis added; see column 4, line 60 through column 5, line 42. Luque thus appear to teach their surgical procedure as involving a conventional dissection to expose the entire area to be treated, and allow insertion of multiple guidewires, screws, and plates spanning multiple vertebrae. Because Luque appear to teach the simultaneous insertion of guidewires and

screws into three or more vertebrae, and adjusting “for lordosis, kyphosis compression or distraction are done with clamps or with a joy stick action with the driver 65 on the screws 15” Luque appears to teach away from performing such a method through the access device of Davison.

The Examiner asserts that Foley teaches a method including the step of inserting a decompression tool into the surgical site to perform a decompression procedure on the vertebrae in order to reduce pressure on the spinal cord. The Examiner has not provided any citation for where in Foley such a teaching can be found. Foley does not appear to teach anything regarding decompression. Rather, Foley appears to teach a method of using a fixed diameter cannula to provide optics and surgical instruments. Foley teaches inserting a tissue retractor or cannulated tissue dilators through the fixed diameter cannula. See column 3, lines 61-65 and column 4, lines 2-4. Foley appears to teach the advantage of their fixed diameter cannula with optics as allowing for percutaneous procedures to be performed in a dry environment without compromising the function of the optics. See column 4, lines 29-31. Foley does not appear to provide any suggestion, guidance, or motivation for performing a decompression procedure. If this rejection is maintained, the Examiner is respectfully requested to point on where in Foley a teaching of a decompression instrument or procedure is found. While Luque do appear to teach performing alignments, decompression, and/or shortening procedures, as discussed above, such procedures are taught as being performed through a conventional dissection of the entire surgical area.

Davison et al. do not appear to teach or suggest what Mathews, Luque, and Foley et al. lack. The Examiner asserts that Davison et al. teach a method including the step of actuating an access device to a second configuration having an enlarged cross-sectional area at the distal portion spanning at least a portion of the first, second, and third vertebrae. The Examiner has not indicated where in Davison et al. such a teaching is found. If this rejection is maintained, the Examiner is respectfully requested to point out where in Davison et al. the asserted teaching is found. Davison et al. appear to teach a method for performing a procedure in which surgical instruments such as steerable instruments, shavers, dissectors, scissors, forceps, retractors, dilators, and video cameras, can be inserted through a cannula. See paragraph [0035]. Claim 20 recites, in part:

performing a two level fixation procedure spanning the first and second interbody spaces through the access device;
advancing a decompression tool through the access device; and
removing a portion of bone from one of the first vertebrae, the second vertebrae, and the third vertebrae through the access device

None of Mathews, Luque, Foley, or Davison et al. appear to teach or suggest such method steps. Similarly, none of the references appears to teach or suggest the specific method steps recited in independent claims 24, 28, or 29. Applicants submit that there is no motivation for one of ordinary skill in the art to use the cannula of Davison et al. for inserting the plates and screws of Mathews or Luque. Further, there is no reasonable expectation of success in performing such a procedure. Mathews and Luque both appear to teach inserting the plates and screws through a conventional incision. Luque specifically teaches a surgical technique in which the entire surgical site appears to be dissected. In view of the specific teaching of Luque of using a conventional incision, and of inserting guidewires and screws into multiple vertebrae and manipulation of the plate using clamps or a driver, there is no expectation of success of performing such a procedure through the access device of Davison et al. Luque appear to teach away from such an access device by teaching the specific surgical technique involving a conventional dissection. Foley et al. appear to teach a method of using a fixed diameter cannula to provide optics and surgical instruments. Davison et al. appear to teach inserting instrument such as shavers, dissectors, scissors, forceps, retractors, dilators, and video cameras through their cannula. Davison et al. do not appear to teach or suggest performing the specific types of procedures recited in the claims through their device. Mathews does not appear to teach his procedure as being performed through any type of cannula, and Applicants submit that one of ordinary skill in the art would have no motivation, guidance, or reasonable expectation of success for inserting the multiple plates and screws of Mathews or Luque through the cannula of Davison et al. Thus, there is no teaching, suggestion, or motivation for one of ordinary skill in the art to combine the procedures of Mathews or Luque and Davison et al. Reconsideration and withdrawal of the rejection are respectfully requested.

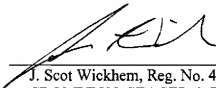
Reconsideration and reexamination are respectfully requested. It is submitted that, in light of the above remarks, all pending claims are now in condition for allowance. If a telephone interview would be of assistance, please contact the undersigned attorney.

Respectfully submitted,
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By their attorney,

Date: _____

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